Message Text

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PAGE 01 STATE 020386

17
ORIGIN OES-05

INFO OCT-01 ARA-10 EUR-12 ISO-00 HEW-06 MED-03 RSC-01 /038 R

DRAFTED BY OES/SCI/BMP:MSBEAUBIEN:KFJ
APPROVED BY OES/SCI/BMP:MSBEAUBIEN
ARA/CEN:JSULLIVAN
HEW/FDA:WEINROTH (DRAFT)
---------- 073036
R 290002Z JAN 75
FM SECSTATE WASHDC
TO AMEMBASSY SAN JOSE
INFO AMCONSUL MILAN
AMEMBASSY LIMA
AMEMBASSY ROME

UNCLAS STATE 020386

E.O. 11652: N/A
TAGS: ETRD, EIND, TBIO, CS
SUBJECT: RECALL OF INCORRECTLY MANUFACTURED AND INCORRECTLY LABELED MEDICAL DEVICE
REF: STATE 4097, MILAN 150 (NOTAL)

1. AMES COMPANY HAS BROUGHT TO HEW/FDA AND DEPT'S ATTENTION THAT THERE MAY HAVE BEEN MISINTERPRETATION IN EMBASSY'S CONTACT WITH MARKET MANAGER REQUESTED IN REFTEL PERHAPS IMPLYING MORE STRINGENT FDA MEASURES MIGHT BE APPLIED.

2. WE BELIEVE USAGE OF TERM "RECALL" AS APPLIED IN FDA REGULATORY PARLANCE MAY LEAD TO MISINTERPRETATION AS IN THIS AND SEVERAL OTHER INSTANCES, SINCE IT COVERS VARIOUS FORMS OF FDA REQUIRED CORRECTIVE ACTION ON THE PART OF MANUFACTURERS RANGING FROM PHYSICAL WITHDRAWL OF THE PRODUCT FROM THE MARKET PLACE TO MODIFICATIONS THAT CAN BE MADE IN THE FIELD. SEPTEL TO POSTS WILL ADDRESS THIS PROBLEM AND WE INTEND TO MODIFY SUBSEQUENT "RECALL" MESSAGES ACCORDINGLY.

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3. SUGGEST EMBASSY CONTACT MARKET MANAGER IN SAN JOSE

AGAIN TO ASSURE HIM THAT QUERY FOR FDA HAS BEEN SOLELY
FOR PURPOSE OF VERIFICATION THAT ULTIMATE RECIPIENTS OF
MEDICAL DEVICE HAVE BEEN NOTIFIED OF CORRECTIVE ("RECALL")

ACTION. MARKET MANAGER SHOULD BE AWARE OF DETAILS
CONCERNING LEVEL OF "RECALL" AND/OR CORRECTIVE ACTIONS
REQUIRED.

4. WE APPRECIATE EMBASSY'S EFFORTS TO ASSIST FDA IN
MEETING LATTER'S RESPONSIBILITIES FOR SAFE AND EFFECTIVE
U.S. MEDICAL PRODUCTS.
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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL CARE, LABORATORY EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 29 JAN 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE020386
Document Source: CORE
Document Unique ID: 00
Drafter: MSBEAUBIEN:KFJ
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750032-0404
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750110/aaaaaijc.tel
Line Count: 73
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN OES
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 75 STATE 4097, 75 MILAN 150
Review Action: RELEASED, APPROVED
Review Authority: greeneet
Review Comment: n/a
Review Content Flags:
Review Date: 20 NOV 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <20 NOV 2003 by MaustMC>; APPROVED <30 DEC 2003 by greeneet>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF INCORRECTLY MANUFACTURED AND INCORRECTLY LABELED MEDICAL DEVICE
TAGS: ETRD, EIND, TBIO, CS, AMES CO
To: SAN JOSE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006